

APR - 1 2004

Attachment 5

510(K) Summary of Safety and Effectiveness

K040081

This 510(K) Summary of Safety and Effectiveness for the LuxV™ handpiece is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(K) summary.

Applicant:	Palomar Medical Technologies, Inc.
Address:	82 Cambridge St. Burlington, MA 01803 781-993-2300
Contact Person:	Marcy Moore
Telephone:	919-363-2432
Preparation Date:	January 12, 2004
Device Trade Name:	Palomar LuxV™ Handpiece
Common Name:	LuxV™
Classification Name:	Laser surgical instrument for use in General and Plastic Surgery and in Dermatology (see: 21 CFR 878-4810). Product Code: GEX Panel: 79
Legally-Marketed Predicate Device:	ClearTouch by Radiancy; Candela Smoothbeam; Laserscope Aura; ICN Photonics NLite
System Description:	The EsteLux Pulsed Light System with the LuxV™ handpiece accessory is a light-based medical device designed for treatment of inflammatory acne.
Intended Use of the Device:	The EsteLux™ System with the LuxV™ handpiece is intended for the treatment of inflammatory acne (acne vulgaris).

Performance Data:

The differences in the specifications of the EsteLux LuxV™ and the ClearTouch do not result in different performance or raise new questions of safety or efficacy. In addition, clinical data was provided to support the safety and efficacy of the LuxV handpiece.

Conclusion:

Based on the foregoing, the LuxV™ handpiece is substantially equivalent to the legally marketed claimed predicate devices.

**DEPARTMENT OF HEALTH & HUMAN SERVICES****Public Health Service**

**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850**

APR - 1 2004

Ms. Marcy Moore
Manager of Clinical Studies
Palomar Medical Technologies, Inc.
131 Kelekent Lane
Cary, North Carolina 27511

Re: K040081

Trade/Device Name: LuxVTM

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: January 13, 2004

Received: January 15, 2004

Dear Ms. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K040081

Device Name: LuxV™

Indications for Use:

The LuxV™ handpiece is intended for the treatment of inflammatory acne (acne vulgaris).

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR
(per 21 CFR 801.109)

Over-the-Counter Use _____

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K040081